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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/362,731	07/29/1999	JEAN-MARIE SAINT-REMY	01699/P.UCB.	7229

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EXAMINER
HUYNH, PHUONG N

ART UNIT	PAPER NUMBER
1644	20

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Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No. 09/362,731	Applicant(s) SAINT-REMY ET AL.	
	Examiner " Neon" Phuong Huynh	Art Unit 1644	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☒ The period for reply expires *4* months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☐ The proposed amendment(s) will not be entered because:

   (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☐ they raise the issue of new matter (see Note below);

   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See Continuation Sheet*.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: *None*.

   Claim(s) objected to: *None*.

   Claim(s) rejected: *18-29*.

   Claim(s) withdrawn from consideration: *15 and 16*.

8. ☒ The proposed drawing correction filed on *02 May 2002* is a)☐ approved or b)☒ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10. ☒ Other: *PTO 948*

Continuation of 5. does NOT place the application in condition for allowance because:

The draft unsingned declaration and amendment to claims 18 and 20 filed on May 2, 2002 are aknowledged.

Claims 18-29 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated compound consisting of SEQ ID NO: 1-5 wherein said compound consisting of one allergen antigenic determinant from Der pII or Der pI which is recognized by B cell (a B cell epitope) linked by two glycine residues to at least one T cell epitope from tetanus toxoid or Influenza which triggers T cell activation for immunizing mice against house dust mite (See page 22 line 25), does not reasonably provide enablement for (1) any isolated compound for preventing or treating any allergy, said compound consisting of one any allergenic determinant which is recognized by a B cell or any antibody secreted by a B cell of a non-atopic individual to any allergen and (b) at least any one antigenic determinant of antigen different from said allergen which triggers T cell activation wherein said allergen is Der pI and Der pII of house dust mite Dermatophagoides pteronyssinus, (2) any compound wherein said any allergenic determinant is not recognized by a T cell, (3) any compound consisting of any allergenic determinant from major antigen of Aspergillus fumigatus, staphylococcal B enterotoxin (SEB) and bovine b-lactoglobulin, or any antibody secreted by a B cell of a non-atopic individual to any allergen such as the ones recited in claim 20, (3) any antigenic determinant of any antigen which triggers T cells activation is any T cell epitope of tetanus toxoid, diphtheria, mycobacterium, influenza or measles virus antigen, (4) any compound wherein the allergenic antigenic determinant and the antigenic determinant of the antigen are any peptidic sequences, (5) any compound wherein peptidic sequences as recited in claim 23 are bound together by a peptidic linker, (6) any compound wherein the peptidic linker comprises at least two of any amino acids, (7) any pharmaceutical composition comprising any compound and pharmaceutical acceptable carrier, (8) any cosmetical composition comprising any compound and a cosmetical acceptable carrier, (9) any beverage, food or feed composition comprising any compound and a liquid, food or feed acceptable carrier, (10) any compound which is used as a medicament and (11) any compound comprises one of the following amino acid sequences selected from the group consisting of SEQ ID NO: 1, SEQ ID NO: 3, SEQ ID NO: 4 and SEQ ID NO: 5 for preventing or treating any allergy. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims for the same reasons set forth in Paper No 19.

Applicants' arguments filed 5/2/02 have been fully considered but are not found persuasive.

Applicants' position is that applicants have amended claim 18 to specifically recite the allergen is "Der pI and Der pII of house dust mite Dermatophagoides pteronyssinus" and applicants have prepared and filed a Rule 1.132 Declaration.

Although applicants have amended claim 18 to recite compound from Der pI and Der pII, there is no structure (SEQ ID NO) associated with function of the term "compound". Further, the phrase "comprises" in amended claim 29 is open-ended. It expands the the amino acid sequence to include additional amin acid residues at either end. Finally, the Declaration is a draft and unsigned.

The specification discloses only (1) a peptide consisting of SEQ ID NO: 2 which is a B cell epitope from Der pII (See page 23), (2) a peptide consisting of SEQ ID NO: 1 mixed with an adjuvant myramyl-dipeptide for immunization (page 25), (3) a peptide consisting of SEQ ID NO: 3 which contains a duplicate T cell epitope derived from tetanus toxoid linked to six repetitive B cell epitopes from Der pII (See page 25, example 2), (4) a peptide consisting of SEQ ID NO: 4 which contains B cell epitopes from Der pI and T cell epitopes from tetanus toxoid (See page 29), (6) a peptide consisting of SEQ ID NO: 5 which contains B cell epitopes from Der pII and T cell epitope from tetanus toxoid (page 29) for immunizing mice against house mite allergen (page 30-32) and (7) a prophetic teachings on the administration of said peptides using a humanized animal model SCID mice and a formulation for a cosmetic composition for skin hygiene on page 32, example 9.

The specification fails to teach how to make and use any compound comprising any B cell epitope from any allergen antigenic determinant mentioned above such as the major antigen from Aspergillus fumigatus, Staphylococcal B enterotoxin and bovine b-lactoglobulin and any antigenic determinant T cell epitope for preventing or treating any allergies. There is insufficient guidance and working examples on any antibody secreted by a B cell to any allergen of a non-atopic individual linked to any antigenic determinant, any pharmaceutical, food, beverage, feed composition for treating or preventing any allergy. Since there is no disclosure on demonstrating the ability of the test mice to withstand challenge from exposure to any allergen after treating any compound mentioned above, it follows that any isolated compound for preventing or treating allergy, including dust mite, is not enabled. Although applicants have amended claim 18 to recite compound from Der pI and Der pII, there is no structure (SEQ ID NO) associated with function of the term "compound". Further, the phrase "comprises" in amended claim 29 is open-ended. It expands the the amino acid sequence to include additional amin acid residues at either end. Given the indefinite number of undisclosed compound, it is unpredictable as to which undisclosed compound would be useful for prevent and treat all allergies.

For these reasons, the specification as filed fails to enable one skill in the art to practice the invention without undue amount of experimentation. As such, further research would be required to practice the claimed invention.

Claims 18-29 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention for the same reasons set forth in Paper No 19.

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Although applicants have amended claim 18 to recite compound from Der pI and Der pII, there is no structure (SEQ ID NO) associated with function of the term "compound". Further, the phrase "comprises" in amended claim 29 is open-ended. It expands the the amino acid sequence to include additional amin acid residues at either end. Finally, the Declaration is a draft and unsigned.

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peptide consisting of SEQ ID NO: 1 mixed with an adjuvant myramyl-dipeptide for immunization (page 25), (3) a peptide consisting of SEQ ID NO: 3 which contains a duplicate T cell epitope derived from tetanus toxoid linked to six repetitive B cell epitopes from Der pII (See page 25, example 2), (4) a peptide consisting of SEQ ID NO: 4 which contains B cell epitopes from Der pI and T cell epitopes from tetanus toxoid (See page 29), (6) a peptide consisting of SEQ ID NO: 5 which contains B cell epitopes from Der pII and T cell epitope from tetanus toxoid (page 29) for immunizing mice against house mite allergen (page 30-32) and (7) a prophetic teachings on the administration of said peptides using a humanized animal model SCID mice and a formulation for a cosmetic composition for skin hygiene on page 32, example 9.

The specification does not reasonably provide a written description of (1) any isolated compound for preventing or treating any allergy, said compound consisting of one any allergenic determinant which is recognized by a B cell or any antibody secreted by a B cell of a non-atopic individual to any allergen and (b) at least any one antigenic determinant of antigen different from said allergen which triggers T cell activation wherein said allergen is Der pI and Der pII of house dust mite Dermatophagoides pteronyssinus, (2) any compound wherein said any allergenic determinant is not recognized by a T cell, (3) any compound consisting of any allergenic determinant from major antigen of Aspergillus fumigatus, staphylococcal B enterotoxin (SEB) and bovine b-lactoglobulin, or any antibody secreted by a B cell of a non-atopic individual to any allergen such as the ones recited in claim 20, (3) any antigenic determinant of any antigen which triggers T cells activation is any T cell epitope of tetanus toxoid, diphtheria, mycobacterium, influenza or measles virus antigen, (4) any compound wherein the allergenic antigenic determinant and the antigenic determinant of the antigen are any peptidic sequences, (5) any compound wherein peptidic sequences as recited in claim 23 are bound together by a peptidic linker, (6) any compound wherein the peptidic linker comprises at least two of any amino acids, (7) any pharmaceutical composition comprising any compound and pharmaceutical acceptable carrier, (8) any cosmetical composition comprising any compound and a cosmetical acceptable carrier, (9) any beverage, food or feed composition comprising any compound and a liquid, food or feed acceptable carrier, (10) any compound which is used as a medicament and (11) any compound comprises one of the following amino acid sequences selected from the group consisting of SEQ ID NO: 1, SEQ ID NO: 3, SEQ ID NO: 4 and SEQ ID NO: 5 for preventing or treating any allergy.

With the exception of specific compound consisting of SEQ ID NOS: 1-5, there is no description about the structure associated with function of any isolated compound mentioned above. Given the lack of a written description as encompassed by the claims, one of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, Applicant was not in possession of the claimed genus. See University of California v. Eli Lilly and Co. 43 USPQ2d 1398. Applicant is directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, paragraph 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

Claims 18-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Bixler et al. (US Patent No 5,785,973, see entire document) for the same reasons set forth in Paper No 19.

Applicants' arguments filed 5/2/02 have been fully considered but are not found persuasive.

Appliants' position is that the present invention are derived from (1) allergen only and are never glycosylated, and (2) the claimed compound consists of at least one allergen antigenic determinant which is recognized by a B cell of a non-atopic individual to said allergen.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., polysaccharide antigens, glycosylated antigen) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The recognition of antigenic determinant of an allergen by B cell of non-atopic individual to said antigen is an inherent properties of the B cell of any individual.

Bixler et al teach a compound which is a conjugate comprising T cell epitope from diphtheria or tetanus toxin which is an antigenic determinant unrelated to B cell determinant (See column 8, lines 5-8, column 8, lines 21-26) conjugated to an antigenic determinant of interest (See column 8, lines 21-30, in particular) such as B cell antigenic determinants of ragweed, mite protein Der pI and Der pII (See column 12, lines 51-60, in particular) for enhance the production of antibodies against common allergen which is particularly useful in the immunization of infant humans whose immune system is not fully developed (See column 8, lines 44-50, in particular). The reference antigenic determinant of T cell epitope from tetanus toxoid, or diphtheria triggers T cell activation and thereof provides T cell help to B cell to increase antibodies production (See column 3, lines 36-52, in particular). The reference compound wherein the allergenic determinant and the antigen determinant of the antigen (T cell epitope) are synthesized by solid phase peptide synthesis which linked the said allergenic determinant and antigenic determinant together via peptide bonds to form a peptidic sequence (See column 16, Procedure for solid phase peptide synthesis, in particular). The reference compound can also be made by linking the allergenic determinant and antigenic determinant via a peptide linker such as lysine or cysteine residues (See column 14, lines 9-24, in particular). Bixler et al also teach a pharmaceutical composition comprising the reference compound and a pharmaceutical acceptable carrier (See column 15, Formulation and administration of vaccine, in particular).

Claim 19 is included in this rejection because the reference B cell antigenic determinant is obviously not recognizes by a T cell since it specifically indicates that it is a B cell and unrelated to B cell determinant.

Thus, the reference teachings anticipate the claimed invention.

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